UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,746	11/20/2003	Jerry Loren McLaughlin	33724/6	8781

32642 7590 08/15/2008

STOEL RIVES LLP - SLC
201 SOUTH MAIN STREET
ONE UTAH CENTER
SALT LAKE CTY, UT 84111

EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,746	MCLAUGHLIN ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9 and 15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/21/08 wherein claims 1-6, 8, and 10-14 were canceled and claims 7, 9, and 15 were amended.

Note: Claims 7, 9, and 15-24 were amended.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 5/21/08 to the rejection of the claims made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejections

The 112, first paragraph, rejection is WITHDRAWN because Applicant amended the claims to overcome the rejections.

112 Second Paragraph Rejections

The 112, second paragraph, rejection is WITHDRAWN because Applicant amended the claims to overcome the rejections.

103 Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 7, 9, and 15-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnayake et al (Evaluation of the pawpaw tree, Asimina triloba (Annonaceae), as a commercial source of the pesticidal annonaceous acetogenins, 1993, pages 644-648) in view of McLaughlin et al (US Patent No. 5,717,113).

In summary, Applicant makes the following assertions. (1) While the crude extract of the instant invention is suitable for administration to a human subject and is standardized for zero percent moisture and exhibits an LC50 of 0.5 ppm in BST, the cited prior art references do not teach or suggest such limitations. (2) Applicant's assert that the Ratnayake et al reference provides an evaluation of the suitability of the pawpaw tree as a commercial source of ***pesticidal*** Annonaceous acetogenins. Furthermore, Applicant asserts that while Ratnayake et al disclose that the acetogenins possess anti-tumor activity, the teachings of the reference focus entirely on the viability of using extracts of the pawpaw tree for pesticidal purposes. (3) The teachings of McLaughlin et al focus on isolating specific acetogenins and acetogenin derivatives as possible therapeutic drugs. In addition, Applicant asserts that McLaughlin et al is not concerned with crude extracts or methods of producing such extracts. (4) Applicant asserts that the combined references would not be in harmony with the intended purposes of the technologies taught by the references.

Applicant's arguments are non-persuasive for the reasons set forth below. First, it is noted that independent claim 15 does not specify that the extract is for human consumption. Also, it is noted that the claim involves the same crude extract moisture percentage and the same LC50 value as the claims which are directed to the extract being suitable for humans. Thus, a skilled artisan would recognize that the extract of independent claim 15 is not limited to human consumption/use only.

In regards to Applicant's assertion that the teachings of Ratnayake et al do not expressly/inherently teach a method having Applicant's desired moisture percentage

and LC50 value in BST, the following response is offered. According to Table I of Ratnayake et al, the table encompasses Applicant's plant part and LC50 value in BST. Thus, a skilled artisan would recognize that if both Applicant and the cited prior art disclose plant parts in BST having overlapping LC50 values, then inherently the properties (i.e., moisture percentage) would be the same/similar. Furthermore, if the water is removed in step (i) which is the same procedure as that which occurs in the art and no water is added, then the percentage of water would be essentially the same.

(The following section addresses Applicant's assertions (3) and (4) above).

In regards to Applicant's assertion (3) above, it should be noted that McLaughlin et al was cited for recognizing the pesticidal activities, like Ratnayake et al, of the acetogenin composition. In addition, the reference was cited for its teachings that the composition may be used as a pharmaceutical formulation for treating a patient having a tumor. The pharmaceutical composition may be formulated in a capsule or tablet (see, for example, McLaughlin et al, abstract; column 4, lines 9-15 and 57-66). Thus, a skilled artisan would recognize that (a) the composition may be used for human consumption and (b) if the composition is in tablet form, the percentage of moisture would essential be zero since the tablet is a compressed granulated material (for definition of a tablet, Applicant is respectfully requested to review any standard medical dictionary such as Dox et al, The Harper Collins Illustrated Medical Dictionary, 1993, page 466). Dox et al defines a 'tablet' as the administering of a compressed granulated material that is administered with a moistening agent such as water or is capable of disintegrating in the presence of saliva. Furthermore, it should be noted that Ratnayake

et al was cited for its teachings about a crude extract, not McLaughlin et al. However, McLaughlin et al disclose that their invention relates to isolation, identification, and use of natural products (column 1, lines 8-12) which include the products of Ratnayake et al which are natural products. Furthermore, Table I of Ratnayake et al is directed to the F005 yield and Example 3 of McLaughlin et al is ***also*** directed to F005. Therefore, one of ordinary skill in the art would be motivated to combine the reference teachings of Ratnayake et al and McLaughlin et al.

Also, while in independent claim 9, for example, the percent moisture is in the range of 10 – 40% moisture with an LC50 in the range of 0.2 - 0.8 ppm in BST , it is noted that in the secondary reference (McLaughlin et al, column 21, lines 61-67) that for F005 (the same species of Table I, pages 7-8, in Ratnayake et al), the BST bioassay disclosed that for its most bioactive fraction, F005, the LC50 was found to be 7.151 X 10^{-1} micrograms/milliliter. If one converts 7.151 X 10^{-1} micrograms/milliliter to ppms, one would get 0.7151 ppm. Note that the LC50 is encompassed within Applicant's designated LC50 range. Hence, it is inherent that the properties of the acetogenin composition of the prior art and Applicant's invention would be the same/very similar.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejections (Written Description)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to other bioactive plan parts that are encompassed by the instant invention. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the

invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed.

Thus, the written description requirement as it relates to 'other bioactive plant parts' is lacking in the instant invention since the disclosure does not describe the other components of a plant that are deemed bioactive such that a person of ordinary skill in the art recognizes what is being claimed.

112 Second Paragraph Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because of the phrase 'other bioactive plant part'. In particular, it is unclear what particular bioactive plant parts Applicant is claiming.

COMMENTS/NOTES

7. Once again, it is noted that review of the provisional application (60/428,602) disclose only the plant part, twigs. Thus, the priority data of the instant invention as it

relates to 'twig' goes back to the provisional application filed 11/22/02. However, for the other plant parts listed in the claims, they are entitled to the filing date of the instant application (11/20/03).

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

August 13, 2008